

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. *Status of the Claims*

Claims 56-67 and 69-70 are pending in this application. No claims are amended. Claims 10, 13 and 44-47 are withdrawn awaiting potential rejoinder should the subject matter of claims 56-67 and 69-70 be found allowable.

II. *Rejections Under 35 U.S.C. § 103(a)*

A. *Rejection over Haarasilta or Poutanen in view of Paice or Wolf and Campbell*

Claims 56-66, 69 and 70 were rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Patent No. 5,176,927 to Haarasilta (“Haarasilta”) or Poutanen, K. (*Trends in Food Science and Technol.* (1997) 8:300-306) (“Poutanen”) in view of Paice et al. (Accession No. P18429, UnitProt Database, 1990 and *Arch. Microbiol.* 1986, Vol. 144:201-206) (“Paice”) or Wolf et al. (Accession No. 140569, PIR Database, 1996 and *Microbiology*, 1995, Vol. 414:281-290) (“Wolf”) and Campbell et al. (U.S. Patent No. 5,405,769) (“Campbell”) Office Action at 3.). Applicants respectfully traverse this rejection.

The Examiner maintains that it would have been obvious to use the bacterial xylanases of Paice, Wolf or Campbell in baking and bakery products as suggested by Haarasilta or Poutanen. Office Action at 5. The Examiner believes that the motivation to combine these references allegedly derives from the disclosure that the addition of xylanases generally to baking products results in improved quality and that Poutanen describes that the addition of xylanases was effective in increasing the specific volume of wheat bread without causing stickiness. *Id.*

1. The Cited Prior Art Teaches Away from the Claimed Invention

The Examiner relies upon Haarasilta and Poutanen as his primary references in the present rejection. Haarasilta discloses the use of xylanases generally in baking products. Haarasilta does not teach or suggest the use of a bacterial xylanase as is presently claimed. Poutanen discusses that the use of xylanases generally may increase viscosity, increase bread volume and decrease staling in bread. The only reference to dough stickiness in Poutanen may be found in Table 3, on page 304. The Table contains a list of effects disclosed for certain xylanases together with a reference to the document which discloses such effects. The Table discloses that a specific fungal xylanase from *Aspergillus* caused an increase in the specific volume of wheat bread without causing stickiness:

A specific *Aspergillus awamori* endo-xylanase was effective in increasing the specific volume of wheat bread without causing stickiness. Maat et al. (1991).

Poutanen at 304. The article cited which disclosed this effect is Maat et al., “Xylanases and their application in bakery”, in Xylans & Xylanases ed. J. Visser *et al.* Elsevier (1992) 349-354 (“Maat”).

References such as Maat (cited by Poutanen and cited as document A27 in the IDS filed on August 18, 2003) actually teach *away* from the use of bacterial xylanases in bakery products or doughs for bakery products, as required by the claimed invention. Specifically Maat states that the use of *Aspergillus awamori* (fungal) xylanase is effective in “increasing the specific volume of breads, without giving rise to a negative side effect on dough handling (stickiness of the dough) *as can be observed with xylanases derived from other fungal or bacterial sources.*” Maat at 349 (emphasis added).

The Examiner alleged that he does not have to consider the disclosure in Maat as the reference was never cited by the Examiner and that the argument is not relevant to the Examiner’s rejection:

[The] examiner would like to state that said reference was never cited by the Examiner in the rejection and the applicants use of the reference in the argument is not relevant to the basis of [the] rejection adopted by the examiner.

Office Action at 10-11. The Examiner further stated that the reference was not relevant as the Examiner had already provided the reason for the use of xylanase isolated by Paice, Wolf, Campbell and Haarasilta:

[The] examiner has provided the reason for the use of xylanases isolated by Paice et al., Wolf et al., Campbell et al., and Haarasilta et al.

Office Action at 11.

Applicants respectfully remind the Examiner that: (1) Maat was cited by Poutanen for the very proposition the Examiner is relying upon in his rejection; and (2) the standard for an obviousness analysis is one of ordinary skill in the art, not the Examiner's perspective.

To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made.

M.P.E.P. § 2142. An obviousness analysis requires what one of skill in the art would have understood the reference to teach. 35 U.S.C. § 103 ("A patent may not be obtained...if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.").

Thus, Applicants maintain that one of ordinary skill in the art reviewing Poutanen would have considered that only the specific *Aspergillus* fungal xylanase cited was effective at increasing the specific volume of wheat bread without causing stickiness. On considering whether the teaching of Poutanen could be applied to other xylanases, a person of ordinary skill in the art would have sought out further information in the form of the cited reference Maat. Maat discloses that the specific fungal enzyme cited in Poutanen, and relied upon by the Examiner, is very effect at increasing specific volumes of breads without giving rise to dough stickiness as is observed with other xylanases derived from other fungal or bacterial sources:

We have identified a particular β -(1,4)-xylanase produced by an *Aspergillus niger* var. *awamori* strain as being very effective in increasing specific volume of breads, without giving rise to a negative side effect on dough handling (stickiness of the dough)

as can be observed with xylanases derived from other fungal or bacterial sources.

Maat at 349 (emphasis added).

The Examiner must rely upon the teaching of the cited art as a whole and how it would be interpreted by one of skill in the art. Maat is being cited by Applicants in order to rebut the Examiner's interpretation of Poutanen and provide support for Applicants' assertion that Poutanen teaches away from the use of bacterial xylanases. In view of the above, and because Maat is cited in Poutanen for the exact proposition the Examiner is relying upon in his rejection (i.e. xylanases improve the stickiness of dough), the Examiner cannot just choose to ignore Maat.

At the time of the claimed invention, bacterial xylanases were known to produce very sticky doughs, as discussed in the specification at paragraphs [0010] - [0012]. Furthermore, Maat discloses that other bacterial xylanases result in negative dough effects such as stickiness. Thus, Applicants maintain that the cited art teaches away from the use of bacterial xylanases as is presently claimed for decreasing dough stickiness.

2. The Examiner Has Provided No Motivation For One of Skill in the Art to Have Selected the Bacterial Xylanase of the Present Invention Over all Other Known Xylanases.

The Examiner maintains that there would have been motivation to select the bacterial xylanases of Paice, Wolf or Campbell as one of skill in the art would have been interested in understanding the effect of the cited xylanases in a bakery product or dough:

[T]hus a skilled artisan would certainly be interested to understand the effect of the xylanase isolated by Paice et al., or Wolf et al., or Campbell et al., on a bakery product or a dough, i.e. its mechanism of action and would be motivated to employ the xylanase isolated by Paice et al., or Wolf et al., and Campbell et al.

Office Action at 11. However, the Examiner has failed to provide a motivation as to why one of skill in the art would have chosen the particular fungal xylanase of Paice, Wolf or Campbell over all other xylanases known at the time of the invention.

Indeed, at the time of the invention, there were vast numbers of xylanases available to chose from. The Examiner has provided no motivation as to why one of skill in the art would have used the specifically claimed bacterial xylanase obtained by expressing the polynucleotide sequence of SEQ ID NO:6 or the xylanase having amino acids 29-213 of SEQ ID NO:5 over all other xylanases which were known in the art. At the time of the claimed invention, bacterial xylanases were known to produce very sticky doughs, as discussed in the specification at paragraphs [0010] - [0012].

In *Takeda Chemical Industries, Ltd. V. Alphapharm Pty., Ltd.*, the Federal Circuit, following and applying *KSR*, held that because the prior art disclosed a large number of compounds without giving a reason for choosing a specific one over the others, a patented claim having that specific compound was held not to be invalid. *Takeda Chemical Industries, Ltd. V. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1359 (Fed. Cir. 2007) (stating that “the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation”).

Here, the prior art disclosed a large number of xylanases, any of which could have been selected to determine their suitability in bakery products. The Examiner has not provided any reason why out of the vast number of known xylanases at the time of the invention, one of skill in the art would have chosen the bacterial xylanase produced by the polynucleotide of SEQ ID NO:6. Additionally, neither Paice, Wolf or Campbell teach or suggest that the disclosed xylanases would have use in particular baking applications. Relying upon impermissible hindsight, the Examiner has arrived at the xylanases disclosed in Paice, Wolf and Campbell based on sequence comparison from Applicants’ disclosure.

3. Applicants’ Claimed Invention Demonstrates Unexpected Results.

The Examiner seems to have disregarded Applicants’ comments in the previous Reply (filed April 11, 2008) regarding Applicants’ discovery that the xylanase produced by the polynucleotide sequence of SEQ ID NO:6 had a surprising and unexpected effect. In particular, the claimed xylanase produced a significantly less sticky dough as compared with other xylanases, including other bacterial xylanases. See Example 1.

In Example 1 of the present application, two fungal xylanases (X1 and Nova) are compared with the bacterial xylanase obtained by expression of the nucleotide sequence of SEQ ID NO:6 (referred to as BX in the captioned application). *See e.g.*, Tables 1 and 2 of the specification. Use of the bacterial BX xylanase resulted in dough that was less sticky than other fungal xylanases. Additionally, Example 1 of the specification compares the Röhm bacterial xylanase (which differs from the xylanase of the present invention by only a small number of amino acids) with the bacterial BX xylanase obtained by expression of the nucleotide sequence of SEQ ID NO:6. *See e.g.* Tables 3 and 4 of the specification. The results in the application demonstrate that BX gave rise to a less sticky dough compared with the Röhm bacterial xylanase.

These results also show that there was a high level of unpredictability in the art with regard to which xylanases would yield less sticky dough. Indeed, the fungal and bacterial xylanases had different effects on the stickiness of the dough produced in the specification. *See e.g.* Table 2 of the specification. Additionally, there are differences in the stickiness of dough produced by different bacterial xylanases. The xylanase produced by the polynucleotide of SEQ ID NO:6 (BX) had a different effect on the stickiness of doughs prepared as compared to another bacterial xylanase (Röhm). *See* Table 4.

4. The Examiner has failed to make a *prima facie* showing of obviousness under the rationale of KSR.

The Examiner stated that the cited references render claims 56-67, 69 and 70 *prima facie* obvious to one of ordinary skill in the art when one applies the Teaching, Suggestion and Motivation test under the following rational for arriving at a “conclusion of obviousness as suggested by the KSR ruling”:

- (1) Combining prior art elements according to known method to yield predictable results.
- (2) Simple substitution of one known element for another to obtain predictable results.
- (3) “Obvious to try” – choosing from a finite number of identified, predictable solution [*sic*], with a reasonable expectation of success.

Office Action at 13. Applicants respectfully disagree.

First, Applicants emphasize that one of skill in the art would not have been able to predict the effects of a bacterial xylanase which is expressed from the nucleotide sequence of SEQ ID NO:6 on dough stickiness. Indeed, as discussed above one of skill in the art would have predicted that a bacterial xylanase would have a negative impact on dough stickiness based on the teaching of Maat, for example. Furthermore, as also discussed above, it was unexpected, and thus unpredictable, that the xylanase expressed from the nucleotide sequence of SEQ ID NO:6 would have resulted in decreased dough stickiness compared to other bacterial and fungal xylanases. None of the references teach or suggest that bacterial xylanases, and in particular the bacterial xylanase expressed from the nucleotide sequence of SEQ ID NO:6, would be effective in decreasing dough stickiness.

Thus, the present invention is not a combination of prior art elements according to known methods which yield predictable results or a simple substitution of one known element for another to obtain predictable results.

Second, Applicants also emphasize that the present invention cannot be considered “obvious to try” as a finite number of identified, predictable solutions did not exist. Furthermore, based on the unpredictability in the art described *supra*, one of skill in the art would not have had a reasonable expectation of success.

Indeed, as discussed *supra*, there were a vast number of xylanases from many different organisms known at the time of the invention which cannot form the basis of a finite number of “identified and predictable solutions” as required by the *KSR* and *Takeda* cases. The Supreme Court in *KSR* established that to sustain a rejection based on a combination of references, there must be a reason to combine elements listed in the prior art. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (US. 2007) (holding that it is important to “identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does”). Thus, the Examiner has failed to provide a reason why one of skill in the art would have chosen the bacterial xylanase produced by the polynucleotide of SEQ ID NO:6 over all other known xylanases.

Applicants thus reiterate that the present claims are nonobvious over the cited prior art in view of the lack of motivation in the art to have specifically chosen the claimed xylanase from all known xylanases, especially in view of the art teaching away from the use of bacterial xylanases. Moreover the claimed invention is nonobvious given the unpredictability in the art and the unexpected results that the claimed xylanase produces a less sticky dough as compared to other xylanases. The Examiner is improperly relying upon hindsight to make the rejection under § 103(a).

B. *Rejection over Haarasilta or Poutanen in view of Paice or Wolf, Campbell and Autio*

The Examiner also rejected claim 67 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Haarasilta or Poutanen, Paice or Wolf and Campbell and further in view of Autio *et al.*, Academic Press, 1996, pages 18-27) (“Autio”). Office Action at 6. The Examiner states that the combination of Haarasilta or Poutanen, Paice or Wolf and Campbell do not specifically teach xylanase free of glucanase enzymes. *Id.* However, the Examiner alleges that Autio teaches “the effects of purified xylanase and glucanase on the structural and baking characteristics of doughs, said reference discloses that the addition of glucanase had a hardening effect on doughs and bakery products.” Office Action at 6-7. The Examiner alleges that it would have been obvious to combine the teachings of Haarasilta, Poutanen, Paice, Campbell and Autio to produce the baking products and doughs with xylanase devoid of glucanase as “the presence of glucanases catalyzes the breakdown of substrates that results in unwanted hardening effect on said products.” Office Action at 7 .

For the reasons discussed above, Autio does not cure the deficiencies of Haarasilta Poutanen, Paice, Wolf and Campbell. Additionally, Autio relates to the use of a purified fungal (*Trichoderma reesei*) xylanase in rye doughs and the effects thereof. *See* Autio, Materials & Methods at 19. Autio does not disclose the use of a bacterial xylanase in dough, let alone a bacterial xylanase expressed from the nucleotide sequence of SEQ ID NO:6. In addition, Autio does not teach or suggest that the use of such a bacterial enzyme will give rise to a less sticky dough compared with an otherwise identical dough prepared by incorporating

a fungal xylanase instead of a bacterial xylanase. Thus, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

III. Conclusion

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date Sept 30, 2008

By Michele M. Simkin

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5538
Facsimile: (202) 672-5399

Michele M. Simkin
Attorney for Applicants
Registration No. 34,717